Section 5: 510(k) Summary

APR 5 2013

In accordance with 21 CFR 807.92 the following summary of information is provided:

Applicant: Bionova Medical, Inc.
3011 Centre Oak Way, Suite 102
Germantown, TN 38138
Ph: (901) 748-2581
Fax: (901) 748-2583

Official Correspondent: Alex Greene
Director Clinical and Regulatory
Bionova Medical, Inc.
Phone: (901) 748-2581
Email: alex@bionovamedical.com

Date of Submission: 18 December 2012

Proprietary Name: Sentrex BioSponge MPD

Common Name: Dressing, Wound, Drug

Regulatory Class: Unclassified

Product Codes: FRO

Predicate Device(s):

- K112191, Sentrex BioSponge Wound Dressing
- K071552, Puracol Plus AG Collagen Microscaffold BioSponge
- K984371, Mepitel Non-Adherent Silicone Dressing
- K083113, ACTICOAT Flex 7 Dressing
- K033869, Contreet Foam Cavity Dressing with Silver
- K081635, INTEGRA Meshed Bilayer Wound Matrix

Device Description:

The Sentrex BioSponge MPD is a sterile, porous, soft chitosan sponge dressing that provides a moist healing environment to support wound healing. The dressing is made of chitosan, a naturally occurring, biodegradable, biocompatible polysaccharide derived from shellfish. The shells are processed and chemically treated. Once in bandage form, they are sterilized by gamma irradiation and packed in a heat-sealed foil laminate pouch. The Sentrex BioSponge MPD may be moistened with saline in accordance with physician recommendation.

When moistened, the Sentrex BioSponge MPD is a highly conformable dressing that maintains contact with the wound surface. The Sentrex BioSponge MPD provides a moist wound environment, which may help minimize wound trauma at dressing changes. *In vivo* data has shown that the Sentrex BioSponge MPD may be used in conjunction with negative pressure wound therapy (NPWT).

The Sentrex BioSponge MPD is provided in the following sizes (l x w x h):

2.5cm x 10cm x 0.6cm	2.5cm x 10cm x 1cm
2.5cm x 20cm x 0.6cm	2.5cm x 20cm x 1cm
5cm x 5cm x 0.6cm	5cm x 5cm x 1cm
5cm x 10cm x 0.6cm	5cm x 10cm x 1cm
5cm x 15cm x 0.6cm	5cm x 15cm x 1cm
10cm x 10cm x 0.6cm	10cm x 10cm x 1cm
10cm x 15cm x 0.6cm	10cm x 15cm x 1cm
10cm x 20cm x 0.6cm	10cm x 20cm x 1cm

Intended Use:

The Sentrex BioSponge MPD is indicated in the dressing and management of:

- Full thickness and partial thickness wounds
- Pressure ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- First and second degree burns
- Donor sites and other bleeding surface wounds
- Abrasions
- Trauma wounds healing by secondary intention
- Dehisced wounds
- Surgical wounds
- Dehisced surgical wounds
- Grafts

The Sentrex BioSponge MPD may be cut to size.

The Sentrex BioSponge MPD is indicated for wounds with moderate to high amounts of exudate, and may be used in conjunction with negative pressure wound therapy (NPWT).

Summary of Technological Characteristics

The Sentrex BioSponge MPD requested for clearance in this submission has the same technological characteristics as the previously cleared Sentrex BioSponge Wound Dressing (K112191). It is a sterile, porous, soft sponge dressing manufactured by a proprietary process from chitosan, a non-toxic, biodegradable, biocompatible, natural-based biopolymer. Chitosan has extensive safety data associated with its use in biomedical applications. Like collagen, chitosan induces a minimal foreign body reaction and retains more moisture than standard gauze, providing a moist environment to support wound healing.

Summary of Nonclinical Testing

New *in vivo* testing has been performed since K112191 was cleared to demonstrate that the Sentrex BioSponge MPD may be used in conjunction with negative pressure wound therapy (NPWT).

Determination of Substantial Equivalence

The claim of substantial equivalence of the Sentrex BioSponge MPD to the predicate devices is based on the comparison of the intended use, device description, product technical/material characteristics, and performance characteristics. Bionova Medical, Inc. considers the Sentrex BioSponge MPD to be as safe and as effective, with substantially equivalent performance to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter dated: April 5, 2013

Bionova Medical, Inc.
% Mr. Alex Greene
Director, Clinical and Regulatory
3011 Centre Oak Way, Suite 102
Germantown, Tennessee 38138

Re: K123961
Trade/Device Name: Sentrex BioSponge MPD
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 05, 2013
Received: March 07, 2013

Dear Mr. Greene:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number: To be assigned

Device Name: Sentrex BioSponge MPD

Indications for Use:

The Sentrex BioSponge MPD is indicated in the dressing and management of:

- Full thickness and partial thickness wounds
- Pressure ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- First and second degree burns
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Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)

Division of Surgical Devices

510(k) Number: K123961

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